

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

*County of Monroe, Michigan v. Purdue Pharma
L.P. et al.,*
Case No. 1:18-op-45158

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**MEMORANDUM OF LAW IN SUPPORT OF THE MANUFACTURER DEFENDANTS’
JOINT MOTION TO DISMISS PLAINTIFF’S SECOND AMENDED COMPLAINT**

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INTRODUCTION AND SUMMARY OF ISSUES AND ARGUMENT

Plaintiff Monroe County’s Second Amended Complaint (“2AC” or “Complaint”) asserts sweeping claims that seek to blame opioid abuse and addiction on a handful of manufacturers of FDA-approved medications (“Manufacturer Defendants”¹). Plaintiff’s familiar narrative ignores the criminal acts of third parties, the crucial role of healthcare providers, and the thorny public policy questions surrounding the problem of opioid abuse. As in all the motions to dismiss before the Court, this motion presents a narrow question: whether Plaintiff pleads a viable *legal claim* against the Manufacturer Defendants. Controlling statutes and case law dictate the answer to that question definitively: Plaintiff does not.

As a threshold matter, the immunity provision of Michigan’s Product Liability Act (“MPLA”) bars Plaintiff’s state law claims. MPLA immunity is broad and absolute. It covers all civil causes of action, by any plaintiff, related to the sale and marketing of any medication where, as here, the FDA has approved the relevant medication and its labeling. Through the MPLA, “the [Michigan] Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that *no tort liability may lie.*” *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003). Although Plaintiff’s 2AC asks the Court to ignore this settled law, it is only for “the Legislature, not this Court, to narrow the application of the statute.” *Att’y Gen. v. Merck Sharp & Dohme*

¹ This Motion incorporates the definition of “Manufacturer Defendants” set forth in the *Summit* MTD at 1 n.2. Defendant Noramco, Inc., a company referenced in the 2AC as a former affiliate of Janssen (*see* 2AC ¶ 51), joins in this Motion to the extent applicable. Noramco does not (and did not at all material times relevant hereto) manufacture, package, brand, market, distribute, or sell the finished drug products at issue in this litigation, and it reserves all rights and defenses specific to it. Conversely, although the arguments raised herein apply equally to Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc, these parties do *not* join this Motion for the same reasons stated in the *Summit* MTD at 1 n.2. Similarly, the arguments also apply to recently named SpecGX LLC, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., as those entities have not yet been served in this action (but intend to join the motion at the appropriate time).

Corp., 807 N.W.2d 343, 350 (Mich. Ct. App. 2011). Plaintiff's state law claims should be dismissed on this basis alone.

Plaintiff's claims fail for other reasons, as well. As described below and in the Manufacturer Defendants' Joint Motion to Dismiss in *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* (Dkt. # 499-1 ("*Summit* MTD")), the 2AC suffers from fundamental flaws, including:

- ***No Standing (All Counts)***. Plaintiff lacks State constitutional authority to bring derivative claims on behalf of the County's residents to address matters of statewide concern.
- ***Preemption (All Counts)***. Plaintiff's claims are preempted because they conflict with the FDA's decisions regarding the approval and labeling of the Manufacturer Defendants' medications.
- ***RICO Claims Fail (Counts 1 and 2)***. Plaintiff's federal RICO claims fail for the same reasons explained in the *Summit* MTD, including the failure to plead RICO standing, causation, actionable racketeering activity, or the existence of a RICO enterprise.
- ***MCPA Safe Harbor (Count 3)***. Plaintiff's claim under the Michigan Consumer Protection Act ("MCPA") is barred by the MCPA's safe harbor, which protects conduct generally authorized by law (like the manufacture and sale of prescription opioids), regardless of whether the specific misconduct alleged is prohibited.
- ***Public Nuisance Not Available (Count 4)***. Michigan law does not impose nuisance liability on manufacturers of allegedly defective products for injuries caused by the purported defect.
- ***Negligence Not Available (Count 5)***. Plaintiff cannot assert a negligence cause of action because the Manufacturer Defendants owe no common law duty to Plaintiff to monitor and report suspicious orders.
- ***Unjust Enrichment and Civil Conspiracy Fail (Counts 6 and 8)***. Plaintiff's unjust enrichment and civil conspiracy claims are derivative of its other defective causes of action and therefore fail for the same reasons.
- ***Fraud Not Available (Count 7)***. Under Michigan law, fraud claims may not be based on alleged misrepresentations made to *third parties*, as opposed to Plaintiff itself.

- ***Statute of Limitations (All Counts)***. Plaintiff's claims, resting as they do on allegations of conduct over a 20-year period, are barred, at least in part, by the applicable statutes of limitation.

Michigan's constitution, legislature, and state courts, as well as the Sixth Circuit, have set clear legal rules governing these issues—rules that compel dismissal of this action. The problem of opioid addiction—or any health crisis, however serious—does not suspend the application of that controlling law. Accordingly, Plaintiff's claims should be dismissed in their entirety.²

ARGUMENT

To survive under Rule 12(b)(6), each claim must be plausible and supported by well-pleaded facts. *Ashcroft v. Iqbal*, 556 U.S. 662, 677-79 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). Further, each of Plaintiff's claims sounding in fraud must satisfy the particularity requirements of Rule 9(b). *See Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 403 (6th Cir. 2012).³ None of Plaintiff's claims meets these standards, as explained below.

I. PLAINTIFF LACKS STATE CONSTITUTIONAL AUTHORITY TO BRING THESE CLAIMS.

As an initial matter, Plaintiff—a single county in the State of Michigan—has no power to bring this lawsuit under the “statewide concern” doctrine as set forth in *In re Certified Question from U.S. Dist. Ct. for E. Dist. of Mich.*, 638 N.W.2d 409 (Mich. 2002). Plaintiff's action infringes on the State's exclusive power to address matters of statewide concern and should therefore be dismissed.

² Pursuant to CMO One § 2.g, the Manufacturer Defendants raise only certain key “issues common to all manufacturers” that warrant dismissal of Plaintiff's claims. They do not raise, and expressly reserve the right to later raise, additional grounds for dismissal of all claims, including Defendant-specific challenges.

³ Pursuant to CMO One, § 2.g., the Manufacturer Defendants incorporate herein the “Legal Standard” section (and other portions, as noted below) of the *Summit* MTD.

It is “well-settled” Michigan law that, under the statewide concern doctrine, a political subdivision’s “power to pass laws, regulations, ordinances or resolutions is . . . *restricted to purely county affairs.*” *Cty. Comm’rs of Oakland Cty. v. Oakland Cty. Exec.*, 296 N.W.2d 621, 629 (Mich. Ct. App. 1980) (citing MCL § 46.11(m)); *accord Arlan’s Dep’t Stores, Inc. v. Kelley*, 130 N.W.2d 892, 895 (Mich. 1964)). “The [Michigan] Constitution does not permit counties to determine legislative policies of Statewide concern, nor does it permit the State legislature to delegate such power.” *Arlan’s Dep’t Stores, Inc.*, 130 N.W.2d at 895.⁴

The power of a Michigan county to sue is likewise limited to matters of “local interest.” *In re Certified Question*, 638 N.W.2d at 414. Here, Plaintiff acknowledges that the opioid crisis is a matter of statewide (and national) concern with effects extending well beyond Monroe County. 2AC ¶¶ 16-18. Just as Plaintiff would be prohibited from passing an ordinance regulating pharmaceutical opioid marketing generally, it cannot bring a lawsuit that seeks to accomplish the same end through injunctive and monetary relief. Plaintiff cites no constitutional provision granting it authority to bring a lawsuit vindicating statewide interests. There is none.

Not only does this lawsuit conflict with the “statewide concern” doctrine, but it also improperly infringes on the constitutional powers of the Attorney General. The Attorney General is a constitutional officer, Mich. Const. 1963, art. 5, § 3, who serves as “[t]he chief law enforcement officer of Michigan.” *Fieger v. Cox*, 734 N.W.2d 602, 604 (Mich. Ct. App. 2007). As the Michigan Supreme Court has made clear, only the Attorney General has the “authority to sue on behalf of the state in matters of state interest.” *In re Certified Question*, 638 N.W.2d at 414. Under Michigan’s constitutional division of powers, a “county is ultimately subordinate to the state” and, although it has the capacity to sue, it cannot usurp the Attorney General’s “broad au-

⁴ In addition, Plaintiff does not and cannot allege that it retains any home rule powers under Michigan law.

thority to sue and settle with regard to matters of state interest, including the power to settle such litigation with binding effect on Michigan's political subdivisions." *Id.* at 414-15.

Indeed, the Attorney General has already exercised his exclusive authority by initiating an investigation of the same core group of Manufacturer and Distributor Defendants based upon the same conduct alleged here—that is, the allegedly improper marketing and sale of opioids. Ex. A. In that investigation, the Attorney General has affirmatively asserted that he “will dig[] into the marketing, distribution and sale of opioids” and “take further coordinated legal action as appropriate.” *Id.* As a county with limited powers, Plaintiff may not infringe on the Attorney General's exclusive authority over these statewide issues. The entire action should be dismissed accordingly.

II. THE MPLA BARS PLAINTIFF'S STATE LAW CLAIMS.

Even if Plaintiff had standing, the MPLA would bar its state law claims. The MPLA prohibits any “product liability action” against a pharmaceutical manufacturer so long as (1) the drug at issue “was approved for safety and efficacy” by the FDA, and (2) “the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer.”⁵ MCL § 600.2946(5); *see Short v. Janssen Pharm., Inc.*, 2015 WL 2201713, at *6 (W.D. Mich. May 11, 2015).

Plaintiff does not challenge either MPLA requirement. Indeed, the Complaint expressly concedes that the Manufacturer Defendants' prescription opioid medications are FDA-approved,

⁵ The MPLA includes two exceptions to immunity, where a defendant (i) bribed or (ii) defrauded the FDA. Neither of those exceptions applies because both require a *federal determination* that the defendant(s) bribed or defrauded the FDA. *See, e.g., Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004); *Ammend v. BioPort, Inc.*, 2006 WL 1050509, at * 3 (W.D. Mich. April 19, 2006) (“[A] plaintiff may not establish the exceptions through proof of fraud or bribery, but instead must show the FDA has made its own determinations of fraud or bribery.”). No such conduct or determinations are alleged here.

and nowhere alleges that their medications' labeling (and accompanying warnings) varied from those that the FDA approved. *See, e.g.*, 2AC ¶¶ 67, 71, 128, 271, 286; *Marsh v. Genentech, Inc.*, 693 F.3d 546, 552-53 (6th Cir. 2012) (finding immunity applied because plaintiff "d[id] not allege that the [drug] she received was adulterated or that its label varied from the label that the FDA approved"). Michigan law therefore prohibits Plaintiff from bringing "product liability actions" related to the marketing and selling of prescription opioids. *See White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1030 (W.D. Mich. 2008) ("The Michigan Legislature provided immunity for drug manufacturers for products approved by the FDA, so long as the product and its labeling meet the FDA standards.").

Plaintiff's claims fall squarely within the definition of "product liability actions" under Michigan law. Michigan has defined "product liability action" broadly to include any legal or equitable theory of liability (1) "brought for the death of a person or for injury to a person or damage to property" (2) "caused by or resulting from the production of a product," which includes marketing and selling. MCL § 600.2945(h). Here, Plaintiff alleges that the Manufacturer Defendants caused Plaintiff to incur costs stemming from an allegedly "false marketing campaign" and the failure to properly "monitor and restrict" the distribution of their medications. *See* 2AC ¶ 1 (describing the "two categories of claims" Plaintiff asserts). Those claims fall within the MPLA's definition of "product liability action" and are therefore prohibited.

First, under the broad scope of the MPLA, Plaintiff's state law claims are an action brought for "injury to a person" in the form of addiction and adverse health effects, and "damage to property" in the form of monetary loss arising from alleged misrepresentations. *Merck Sharp*, 807 N.W.2d at 350 ("[P]laintiffs' claim of monetary loss based on alleged misrepresentations

regarding the safety and efficacy of Vioxx constitutes a claim for damage to property.”).⁶ *Second*, all of Plaintiff’s claims relate to the Manufacturer Defendants’ “production” of prescription opioids. Under Michigan law, “production” is defined broadly to include “a myriad of activities a manufacturer might perform related to the product,” *White*, 538 F. Supp. 2d at 1030, including, as relevant here, “manufacture[,] . . . formulation, development of standards[,] . . . certifying, warning, instructing, *marketing*, *selling*, advertising, packaging, or labeling.” MCL § 600.2945(i). By their own terms, Plaintiff’s claims fault the Manufacturer Defendants for the “production” of their opioid products, including by (i) engaging in the “deceptive *marketing*” of opioids and (ii) “*selling* opioids without maintaining effective controls against . . . diversion.” 2AC ¶¶ 864, 866-77, 882.

Indeed, the Michigan Court of Appeals rejected a similar lawsuit in which the Michigan Attorney General sought to recover government funds paid because of a pharmaceutical manufacturer’s allegedly fraudulent representations regarding its prescription medication. *Merck Sharp*, 807 N.W.2d 343, *leave to appeal denied*, 803 N.W.2d 696 (Mich. 2011). The court held: “Viewing the complaint in its entirety, the substance of plaintiffs’ claims concerns the safety and efficacy of [defendant’s] drug and [defendant’s] representations in that regard. Because the FDA approved the safety and efficacy of [that drug], plaintiffs’ claims are barred.” *Id.* at 350. Here too, Plaintiff’s claims ultimately concern the safety and efficacy of the Manufacturer Defendants’ FDA-approved medications, and they should be dismissed accordingly.

Plaintiff’s allegations that certain Manufacturer Defendants “engaged in off-label market-

⁶ Michigan’s interpretation of “damage to property” for purposes of the MPLA does not change the fact Plaintiff has not suffered an injury to its “business or property” sufficient to confer federal RICO standing. *See Summit* MTD § II.A.2. As used in the RICO statute, the term “business or property” “retains restrictive significance” in accordance with RICO’s narrow “federal statutory purpose.” *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 564-65 (6th Cir. 2013).

ing” or “misbrand[ed]” their products cannot defeat immunity. 2AC ¶¶ 42, 628. The MPLA applies regardless of whether a plaintiff alleges that defendants promoted products for “off-label” uses or even “misbranded” them. *See Cotton v. Johnson & Johnson*, 2016 WL 9776137, at *3 (E.D. Mich. Dec. 1, 2016) (“Plaintiff claims that defendant has admitted to misbranding Risperdal and selling it for purposes for which it was not approved. Even if these allegations are true . . . plaintiff’s argument cannot overcome defendant’s immunity, and plaintiff’s claims must be dismissed.”), *aff’d*, 2017 WL 4857552 (6th Cir. Sept. 22, 2017); *White*, 538 F. Supp. 2d at 1029 (dismissing complaint as barred by MPLA even though plaintiffs “allege[d] a nefarious campaign by Defendant to influence the medical community into prescribing [its medication] ‘off-label’”).

That Plaintiff’s claims are not expressly styled as “product liability” actions likewise makes no difference. In determining whether immunity applies, “[a] court is not ‘bound by a party’s choice of labels for its action because this would put form over substance.’” *Cotton*, 2016 WL 9776137, at *3 (quoting *Duronio v. Merck & Co., Inc.*, 2006 WL 1628516, at *3 (Mich. Ct. App. June 13, 2006)). “Instead, a court should examine the content of the claims to determine whether a plaintiff is in substance bringing a product liability action.” *Id.* To that end, courts have repeatedly dismissed a variety of causes of action—including many of the same ones brought here—based on the immunity provided by the MPLA. *See Merck Sharp*, 807 N.W.2d at 350 (unjust enrichment); *Griffus v. Novartis Pharm. Corp.*, 2006 WL 2583129, at *1 (E.D. Mich. Sept. 6, 2006) (negligence); *Duronio*, 2006 WL 1628516, at *5 (fraud).

In sum, “the Michigan Legislature made a policy judgment intending to shield drug manufacturers from liability,” *Devore v. Pfizer Inc.*, 58 A.D.3d 138, 141 (N.Y. App. Div. 2008), and there is no way to circumvent that result. *See Cotton*, 2016 WL 9776137, at *3 (“[P]laintiff cor-

rectly comprehends that the MPLA effectively prohibits him from pursuing his claims against defendant, and is understandably frustrated.”); *see also Taylor*, 658 N.W.2d at 131 (“[A] manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a products liability claim.”). The Court should therefore dismiss each of Plaintiff’s state law claims (Counts 3-8) as barred by the MPLA.

III. PLAINTIFF’S STATE LAW CLAIMS ARE PREEMPTED (COUNTS 3-8).

As in *Summit*, Plaintiff’s state law claims should also be dismissed for the independent reason that they are preempted. As explained in the *Summit* MTD, these claims cannot survive because they conflict with the FDA’s decisions regarding the approval and labeling of the Manufacturer Defendants’ medications and the FDA’s exclusive enforcement authority with respect to off-label and misleading promotion, as well as the FDA’s decision to approve the manufacture and sale of these medications to the public. *See Summit* MTD § IV.

IV. PLAINTIFF’S MICHIGAN CONSUMER PROTECTION ACT CLAIM FAILS (COUNT 3).

A. The Manufacturer Defendants’ Alleged Conduct Is Protected by the MCPA’s Safe Harbor.

The Michigan Consumer Protection Act (“MCPA”) expressly exempts from liability “transaction[s] or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States.” MCL § 445.904(1)(a). In determining whether this exemption applies, courts must focus on “whether the [general] transaction at issue, *not the alleged misconduct*, is specifically authorized.” *Liss v. Lewiston-Richards, Inc.*, 732 N.W.2d 514, 518 (Mich. 2007) (emphasis in original). If “the general transaction is specifically authorized by law,” the MCPA will not apply “regardless of whether the specific misconduct alleged is prohibited.” *Id.* at 519. This exemption reaches broadly to restrict liability for any regulated industry and activity. For example, a homebuilder

cannot be held liable under the MCPA for misconduct related to constructing a home because the general transaction of homebuilding is “specifically authorized” under Michigan’s regulatory scheme. *Id.* at 520. Nor can an insurance company be liable under the MCPA for misrepresentations about an insurance policy.⁷ *Smith v. Globe Life Ins.*, 597 N.W.2d 28, 38 (Mich. 1999). As long as the “general transaction” is authorized by law, the MCPA does not apply to any alleged misconduct related to that transaction.

So too here. The marketing, selling, and reporting activities that Plaintiff challenges are both “specifically authorized” and heavily regulated by federal law. *See, e.g.*, 21 U.S.C. § 301 *et seq.* (FDCA); 21 U.S.C. § 355-1 (governing REMS programs); 21 C.F.R. § 201.1 *et seq.* (labeling), § 202.1 (prescription drug advertising); § 203.1 *et seq.* (prescription drug marketing); 21 U.S.C. § 801 *et seq.* (CSA); 21 C.F.R. §§ 1301 (registration and security controls); 1302 (labeling and packaging); 1303 (quotas); 1304 (records and reports). The Complaint itself acknowledges that the FDA oversees and regulates all of the Manufacturer Defendants’ marketing activities, *see, e.g.*, 2AC ¶¶ 130, 137, 144, 160-64, 222, 232, 242, 271, 276, 287-92, 421, 433-34, 447, including through industry trade groups, *see, e.g., id.* ¶¶ 320, 396, and that federal law specifically authorizes unbranded advertising too, *see, e.g., id.* ¶ 405. The Complaint also acknowledges that prescription opioids are “regulated at the federal level” by the DEA, *id.* ¶ 96, and that the DEA specifically authorizes (and indeed, sometimes requires) a controlled substance monitoring and reporting program, *see, e.g., id.* ¶¶ 459-60, 468-76, 478, 483, 764, 819(h)(10), 876. Michigan similarly regulates the Manufacturer Defendants’ manufacturing activities. *See, e.g.*, MCL

⁷ Similarly, the MCPA does not apply to a casino and slot-machine manufacturer for allegedly deceptive practices related to state-authorized gambling activities, *Kraft v. Detroit Entm’t, L.L.C.*, 683 N.W.2d 200, 204-05 (Mich. Ct. App. 2004), or a bank for imposing fees regulated by federal law, *Molosky v. Wash. Mut., Inc.*, 664 F.3d 109, 118 (6th Cir. 2011); *Newton v. West*, 686 N.W.2d 491, 493-94 (Mich. Ct. App. 2004).

§ 333.7303; 2AC ¶ 633-34. Plaintiff's allegations that the Manufacturer Defendants committed misconduct in the course of their marketing and monitoring activities make no difference. The MCPA exemption applies "regardless of whether the specific misconduct alleged is prohibited" by law, as long as, like here, the "general transaction" is authorized. *Liss*, 732 N.W.2d at 519; *accord Smith*, 597 N.W.2d at 38; *Molosky*, 664 F.3d at 118; *Newton*, 686 N.W.2d at 494; *Kraft*, 683 N.W.2d at 205.

B. The Manufacturer Defendants' Alleged Conduct Is Not "In the Conduct of Trade or Commerce" Under the MCPA.

Count 3 also fails because the MCPA prohibits only those unfair and deceptive acts "in the conduct of *trade or commerce*." MCL § 445.903(1). "Trade or commerce" "means the conduct of a business providing goods, property, or service primarily for *personal, family, or household purposes*." *Id.* § 445.902(1)(g). Put another way, "the MCPA applies only to purchases by *consumers*," not purchases "for business purposes." *Slobin v. Henry Ford Health Care*, 666 N.W.2d 632, 634 (Mich. 2003).

The Manufacturer Defendants' sales of prescription opioids simply do not qualify as acts in the conduct of trade or commerce, as the Manufacturer Defendants do not sell their FDA-approved prescription opioids to "consumers." Rather, the Manufacturer Defendants sell opioids only to licensed physicians, hospitals, pharmacies, and other businesses—who, in turn, then prescribe or sell the prescription opioids in the course of their respective business operations. And Plaintiff does not qualify as a "consumer" capable of invoking the MCPA, since it does not allege that it made any specific purchase of prescription opioids, much less for personal, family, or household purposes. By its own terms, the MCPA therefore does not apply to the Manufacturer Defendants' sales or to Plaintiff's municipal expenditures. *See MacDonald v. Thomas M. Cooley L. Sch.*, 724 F.3d 654, 660 (6th Cir. 2013) (The MCPA "does not cover purchases . . . for busi-

ness or commercial purposes.”); *Pa. Emp., Benefit Tr. Fund v. Zeneca, Inc.*, 710 F. Supp. 2d 458, 484 (D. Del. 2010) (dismissing MCPA claim because the MCPA did not apply to payment of prescription medicines by third-party payor); *Slobin*, 666 N.W.2d at 634 (MCPA does not apply to law firm’s purchase of medical records from healthcare provider); *Zine v. Chrysler Corp.*, 600 N.W.2d 384, 394 (Mich. Ct. App. 1999) (MCPA does not apply to purchase of truck primarily used for business purposes); *Timber Prod. Inspection, Inc. v. Coastal Container Corp.*, 827 F. Supp. 2d 819, 834 (W.D. Mich. 2011) (MCPA does not apply to sale of corrugated packaging and packaging supplies).

Moreover, the MCPA “does not allow for the creation of a duty where none otherwise exists.” *Hayner v. Old Kent Bank*, 2002 WL 227016, at *1 (Mich. Ct. App. Feb. 12, 2002). As explained in the *Summit* MTD § III.A, the Manufacturer Defendants’ alleged monitoring and reporting duties are owed only *to the federal government*, not to consumers. And under Michigan’s “learned intermediary” doctrine, prescription medication manufacturers have “a legal duty to warn” only “the medical profession, *not the patient*, of any risks inherent in the use of the drug.” *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 479 (Mich. 1979). The MCPA is thus doubly inapplicable here, because the Manufacturer Defendants have no duty running directly to Plaintiff (much less to individual patients who receive prescriptions).

C. Plaintiff Does Not Allege Unfair or Deceptive Practices with Particularity.

Even if the MCPA applied here, Plaintiff has failed to plead the “who, what, when, where, and how” of the Manufacturer Defendants’ alleged fraud with the requisite particularity, as explained *infra* § VIII. See *Traxler v. PPG Indus., Inc.*, 158 F. Supp. 3d 607, 630 (N.D. Ohio 2016) (MCPA claims based on alleged misrepresentations must satisfy Rule 9(b)); see also *Summit* MTD §§ II.B.4, X. Plaintiff does not provide the particular details of a single alleged misrepresentation or omission made in Monroe County.

Moreover, the alleged misrepresentations do not violate the MCPA's substantive provisions. An MCPA plaintiff must allege "that a reasonable person would have relied on the [allegedly false or misleading] representations," *Dix v. Am. Bankers Life Assurance Co. of Fla.*, 415 N.W.2d 206, 209 (Mich. 1987), or that the misrepresentations would mislead a reasonable person, MCL § 445.903(1)(s); *see* 2AC ¶ 853. Yet nowhere does the Complaint allege facts to show that a reasonable physician would have been misled by any Manufacturer Defendant's marketing materials in light of the FDA-approved labeling that accompanies their prescription opioids. Indeed, Plaintiff does not identify even a single prescriber in Monroe County who allegedly received and then relied on the Manufacturer Defendants' marketing materials to the exclusion of the FDA-approved labeling and the prescriber's own independent medical judgment—let alone a *reasonable* prescriber who did so. Plaintiff has thus failed to plead this essential element of an MCPA claim.

D. Plaintiff Cannot Show Causation or Damages.

Only a person "who suffers loss *as a result of* a violation of" the MCPA may maintain an action. MCL § 445.911(2). As explained in the *Summit* MTD § II.B, however, Plaintiff has not shown any loss "as a result of" the Manufacturer Defendants' alleged conduct. Indeed, Plaintiff has not shown any "loss" or "actual damages" under the MCPA at all. MCL § 445.911(2). Under the MCPA, recoverable damages include only "the difference between the actual value of the property when the contract was made and the value that it would have possessed if the representations had been true." *Van Vels v. Premier Athletic Ctr. of Plainfield, Inc.*, 182 F.R.D. 500, 509 (W.D. Mich. 1998). Despite alleging a laundry list of purported losses, *see* 2AC ¶¶ 651-64, Plaintiff has not alleged that it *ever* purchased even a single prescription opioid itself. *Cf. id.* ¶ 664. Nor, for that matter, has Plaintiff alleged that the "actual value" of any prescription opioid prescribed in Monroe County within the limitations period was any less than what was paid.

Plaintiff has thus failed to allege a cognizable “loss” under the MCPA. *Van Vels*, 182 F.R.D. at 509.

V. PLAINTIFF’S PUBLIC NUISANCE CLAIM FAILS (COUNT 4).

Plaintiff’s public nuisance claim also fails because, among other reasons, (1) the MPLA provides an absolute defense; and (2) the claim is preempted. *See supra* §§ II-III; *Summit* MTD §§ II.B.1-2, III.B.1-2, VII; *infra* § X. The claim also fails for the reasons that follow.

A. Plaintiff Fails to Allege the Elements for a Public Nuisance Claim.

Like Ohio and Illinois, Michigan law defines a public nuisance as “an unreasonable interference with a common right enjoyed by the general public.” *Cloverleaf Car Co. v. Phillips Petroleum Co.*, 540 N.W.2d 297, 300 (Mich. Ct. App. 1995) (affirming dismissal of public nuisance claim); *Adkins v. Thomas Solvent Co.*, 487 N.W.2d 715, 720 n.8 (Mich. 1992) (citing Restatement (Second) of Torts § 821B(2)). As explained in the *Summit* MTD and the Manufacturer Defendants’ Motion to Dismiss in the *City of Chicago v. Purdue Pharma L.P. et al*, No. 1:17-op-45169 (Dkt. # 500-1) (“*Chicago* MTD”), allegations like Plaintiff’s do not meet this definition. *Summit* MTD § VII; *Chicago* MTD § II. The same analysis in *Summit* and *Chicago* applies under Michigan law.

No public right. As in Ohio and Illinois, “[t]o be considered public, the nuisance must affect an interest common to the general public, rather than peculiar to one individual, or several.” *Twp. of Garfield v. Young*, 82 N.W.2d 876, 879 (Mich. 1957) (quoting Prosser, Handbook of the Law of Torts § 71). Thus, in *Detroit Board of Education v. Celotex Corp.*, the Court of Appeals of Michigan held that “manufacturers . . . of defective products may not be held liable on a nuisance theory for injuries caused by the defect.” 493 N.W. 2d 513, 521 (Mich. Ct. App.

1992). “To hold otherwise,” the court reasoned, “would significantly expand, with unpredictable consequences, the remedies already available to persons injured by products.”⁸ *Id.*

No unreasonable interference. Michigan courts have adopted the Restatement of Torts’s definition of public nuisance, and the Supreme Court of Michigan has followed the Restatement’s provisions on nuisance law. *See, e.g., Sholberg v. Truman*, 852 N.W.2d 89, 101 (Mich. 2014); *Adkins*, 487 N.W.2d at 720. The Restatement’s commentary on that definition provides: “Although it would be a nuisance at common law, conduct that is fully authorized by statute, ordinance or administrative regulation does not subject the actor to tort liability.” Restatement (Second) Torts § 821B cmt. f.

Here, the manufacture, promotion, and sale of opioid analgesics are authorized and extensively regulated by federal and state law. *See, e.g., Summit* MTD § VII.C (collecting federal statutes and regulations); MCL §§ 333.7214, 333.7303, 333.7303a. Plaintiff’s conclusory allegation that the Manufacturer Defendants’ conduct “violated Michigan and federal law by engaging in the deceptive marketing of opioids,” 2AC ¶ 864, is insufficient to plead a violation, and Plaintiff has not otherwise pleaded its false or deceptive marketing claims with the particularity required by Rule 9(b). *See Summit* MTD § II.B.4. Further, Plaintiff does not support its bare conclusory allegation that the Manufacturer Defendants have violated laws against diversion (2AC ¶ 868) with factual allegations of conduct by any Manufacturer Defendant that would violate any federal or state law. *See infra* § X.

⁸ The trial court order in *Archer v. Arms Technology, Inc.*, 2000 WL 35624356 (Mich. Cir. Ct. May 16, 2000), which allowed a public nuisance claim to proceed against gun manufacturers and distributors, was reversed on other grounds on appeal without discussion of the public nuisance holding, 669 N.W. 2d 845 (Mich. Ct. App. 2003), and thus is not indicative of how the Michigan Supreme Court would approach the issue of a public right. In any event, the risk of physical injury on public streets created by guns is significantly different from the direct individual harms alleged from opioid use for chronic pain.

Lack of causation. Finally, Plaintiff’s public nuisance claim fails because the Manufacturer Defendants’ alleged actions did not actually or proximately cause the harms alleged by Plaintiff. Like the plaintiff in *Summit County*, Plaintiff alleges that the Manufacturer Defendants marketed their opioid medications deceptively (2AC ¶¶ 863-64) and failed to prevent the diversion of their products to secondary markets (*id.* ¶¶ 865-67); and as a result, Plaintiff incurred increased costs for municipal services (*id.* ¶ 870). As explained in the *Summit* MTD, Plaintiff’s generalized allegations lack well-pleaded facts making plausible a conclusion that the alleged misconduct was the but-for cause of the opioid crisis. *Summit* MTD §§ II.B.1, III.B.1. Moreover, the chain of causation for this theory involves numerous links, which are broken by intervening acts by third parties, including patients, doctors and pharmacies—over whom the Manufacturer Defendants have no control—who diverted medications for illegal purposes in violation of both state and federal law. *Summit* MTD § II.B.2, III.B.2 (citing federal laws); *City of Chicago* MTD § II.A; *Hobrla v. Glass*, 372 N.W.2d 630, 634-35 (Mich. Ct. App. 1985). The chain of causation is also broken by the role of doctors as learned intermediaries who are presumed to have read and understood the warning labels on the Manufacturer Defendants’ opioids. *Summit* MTD § II.B.2; *infra* § X.B.1. Plaintiffs thus fail to plead each and every required element of a claim for public nuisance.

B. The Michigan Supreme Court Likely Would Adopt The Municipal Cost Recovery Rule, Which Precludes Recovery Here.

Although not necessary to dispose of Plaintiff’s claims, the municipal cost recovery rule (or “free public services” doctrine) provides that “public expenditures made in the performance of governmental functions are not recoverable in tort.” *City of Chi. v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1144 (Ill. 2004); *see Chicago* MTD at 25. That includes the costs of public services to abate a public nuisance. *See Beretta*, 821 N.E.2d at 1147. No published Michigan deci-

sion appears to have explicitly adopted or rejected the doctrine. The Manufacturer Defendants submit that the State's high court would, if presented with the issue, follow the Supreme Court of Illinois's careful and thorough reasoning and adopt the municipal cost recovery rule as Michigan law. *See id.* at 1143-47. Plaintiff's attempt to recover for the costs of its public services thus should be precluded under the municipal cost recovery rule. *Id.*

VI. PLAINTIFF'S NEGLIGENCE CLAIM FAILS (COUNT 5).

Plaintiff's negligence claim fails for many of the reasons discussed above: (1) the MPLA provides an absolute defense; (2) Plaintiff fails to plead actual and proximate causation; (3) the claim is preempted; (4) the claim is barred by the municipal cost recovery rule; and (5) Plaintiff fails to plead any actionable conduct, including with the particularity required by Rule 9(b). *See supra* §§ II, III, IV.B. In addition, for the reasons set forth in the *Summit* MTD (and the Distributor Defendants' motion to dismiss in the same matter), Plaintiff's negligence claim should be dismissed because the Manufacturer Defendants do not have a common law duty to Plaintiff to monitor and report suspicious orders. *See Summit* Distributors' MTD (Dkt. 491-1) § III.B; *see also Summit* MTD § III.B.4.a. Finally, to the extent that Plaintiff purports to bring a claim of negligence *per se*, *see* 2AC ¶ 874, this claim fails because Plaintiff has not alleged a violation of any predicate statute or regulation that allows for a private right of action. *See Zeni v. Anderson*, 243 N.W.2d 270, 280 (Mich. 1976); *Rush v. Mac*, 792 F.3d 600, 605 (6th Cir. 2015) (recognizing that where federal statute "does not create a private right of action, and that Michigan courts have not recognized that the [federal] regulations impose a duty of care" the court was not authorized to impose new liabilities); *Summit* MTD § IX.

VII. PLAINTIFF'S UNJUST ENRICHMENT CLAIM FAILS (COUNT 6).

Plaintiff's unjust enrichment claim is derivative of its other claims and thus falls with them. *See, e.g., Taylor v. Kochanowski*, 2010 WL 2696675, at *3 (Mich. Ct. App. July 8, 2010).

Plaintiff's claim also fails on its own terms. Plaintiff must allege that *it* conferred a *direct* benefit on the Manufacturer Defendants. *Lipov v. Louisiana-Pacific Corp.*, 2013 WL 3805673, at *6 (W.D. Mich. July 22, 2013); *W.C. Ducomb Co. v. Ann Arbor Mach. Co.*, 2012 WL 516089, at *3-4 (Mich. Ct. App. Feb. 16, 2012). As in *Summit*, Plaintiff's claim fails because Plaintiff has not entered into a direct transaction with any Manufacturer Defendant. *See Summit* MTD § XII; *Lipov*, 2013 WL 3805673, at *6.

VIII. PLAINTIFF'S FRAUD CLAIM FAILS (COUNT 7).

In addition to the reasons outlined *supra* §§ II, V.B, Plaintiff's fraud claim fails for the same reasons set forth in the *Summit* MTD § X.

In Michigan, "to establish a claim of fraudulent misrepresentation, *the plaintiff* must have reasonably relied on the false representation." *Cummins v. Robinson Twp.*, 770 N.W.2d 421, 435 (Mich. Ct. App. 2009) (per curiam). Plaintiff's conclusory allegations of reliance, 2AC ¶ 893, and of the effect of marketing on prescribers, *id.* ¶ 892, are plainly insufficient. *Evans v. Pearson Enters., Inc.*, 434 F.3d 839, 852-53 (6th Cir. 2006) ("Conclusory statements of reliance are not sufficient to explain with particularity how she detrimentally relied on the alleged fraud."). Under Michigan law, "[a]n allegation of fraud based on misrepresentations made to a third party does not constitute a valid fraud claim." *Int'l Bhd. of Elec. Workers, Local Union No. 58 v. McNulty*, 543 N.W.2d 25, 30 (Mich. Ct. App. 1995). That is especially true here, where Plaintiff's bare allegations fail to establish even third-party reliance. *See Evans*, 434 F.3d at 852-53. Indeed, Plaintiff does not identify any Monroe County prescriber or resident who saw or heard any alleged misrepresentation, much less wrote or sought an allegedly medically unnecessary prescription as a result.

Finally, there can be no fraud where, as here, "a person has the means to determine that a representation is not true." *Cummins*, 770 N.W.2d at 435; *see also Pizza Hut, Inc. v. Papa John's*

Int'l, Inc., 227 F.3d 489, 495 n.5 (5th Cir. 2000) (an allegedly misleading “statement must be viewed in the light of the overall context”). The Manufacturer Defendants’ FDA-approved labels on their opioid medications carry prominent warnings that disclose the risks of addiction, abuse, misuse, overdose, and death. *See Summit MTD* § II.B.4. These labels were given to prescribing physicians (who are obligated by law to know their content), and thus “the allegedly defrauded party was given direct information refuting the misrepresentations.” *Titan Ins. v. Hyten*, 817 N.W.2d 562, 555 n.4 (Mich. 2012). “As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers.” *Mowery v. Crittenton Hosp.*, 400 N.W.2d 633, 637 (Mich. Ct. App. 1986) (per curiam). For each independent reason just discussed, Plaintiff’s fraud claim fails.

IX. PLAINTIFF’S CIVIL CONSPIRACY CLAIM FAILS (COUNT 8).

Under Michigan law, a claim for civil conspiracy is entirely derivative of tort claims “and unless something is actually done by one or more of the conspirators which results in damage, no civil action lies against anyone.” *Roche v. Blair*, 9 N.W.2d 861, 864 (Mich. 1943); *see id.* (“Accurately speaking, there is no such thing as a civil action for conspiracy.”); *Saloka v. Shelby Nursing Ctr. Joint Venture*, 2005 WL 3304596, at *8 (Mich. Ct. App. Dec. 6, 2005). Because Plaintiff has not adequately alleged any underlying claims, the derivative conspiracy claim fails as a matter of law. *See Kerrigan v. ViSalus, Inc.*, 112 F. Supp. 3d 580, 616 (E.D. Mich. 2015).

In addition, Plaintiff fails to allege even the basic elements of a conspiracy. Michigan law requires a plaintiff to plead with particularity the “proof of an agreement to achieve the objective of the conspiracy.” *Knight Indus. & Assocs., Inc. v. Euro Herramientas, S.A.U.*, 2013 WL 3773373, at *5 (E.D. Mich. July 17, 2013) (quoting *Admiral Ins. v. Columbia Cas. Ins.*, 486 N.W. 2d 351, 358 (Mich. Ct. App. 1992)). Plaintiff’s conclusory allegations, 2AC ¶¶ 665, 678,

899, fail to plead the existence of a conspiratorial agreement between *any* of the separate and distinct Defendants and should therefore be dismissed. *See Summit* MTD § XIII; *Knight Indus. & Assocs., Inc.*, 2013 WL 3773373, at *5.

X. PLAINTIFF’S RICO CLAIMS FAIL FOR THE SAME REASONS AS IN *SUMMIT* (COUNTS 1 AND 2).

Finally, Plaintiff’s (1) RICO “Marketing Enterprise” and (2) RICO “Supply Chain Enterprise” claims fail for the same reasons explained in the *Summit* MTD. Plaintiff’s RICO allegations echo those in the *Summit* complaint nearly *verbatim*, with “Michigan” simply replacing “Ohio.” *Compare* 2AC ¶¶ 728-91 (facts), ¶¶ 792-818 (Count 1), and ¶¶ 820-50 (Count 2) *with Summit* Corrected 2AC ¶¶ 814-77 (facts), ¶¶ 878-904 (Count 1), and ¶¶ 906-37 (Count 2).⁹ Indeed, the 2AC’s RICO allegations are even weaker than *Summit* in some respects. Unlike *Summit County*, Plaintiff has not even alleged that it interviewed a single Monroe County prescriber before filing suit. *See Summit* Corrected 2AC ¶ 675-76, 678-79.

Moreover, Plaintiff cannot plead the elements of a RICO claim based on Michigan law. Indeed, the controlling principles under Ohio law that precluded plaintiff’s RICO claims in *Summit* apply with equal force here:

- ***No causation.*** Plaintiff fails to allege causation because, among other things, Plaintiff’s causal theory depends on alleged acts of diversion by patients, doctors, and pharmacies that violate both federal and Michigan law. MCL § 333.7401 (imposing penalties on practitioners who dispense or prescribe a controlled substance for an illegitimate purpose); *id.* § 333.7403 (unlawful for individual to possess controlled substance without valid prescription); *id.* § 333.7333 (providing that a prescriber shall not issue false prescriptions and pharmacists shall act in good faith in dispensing controlled substances).
- ***No actionable racketeering activity.*** Plaintiff’s theory that the Manufacturer Defendants committed predicate acts of fraud by misrepresenting their compliance with state law duties to monitor, report, and halt suspicious orders fails because

⁹ The paragraphs describing the requested relief in Counts 1 and 2 appear to be swapped. *Compare* 2AC ¶ 819 and ¶ 851 *with Summit* Corrected 2AC ¶ 938 and ¶ 905, respectively.

Michigan imposes no independent statutory or common law duties to do so. *See Murdock v. Higgins*, 559 N.W.2d 639, 642 (Mich. 1997) (“Generally, an individual has no duty to protect another who is endangered by a third person’s conduct.”).

- ***No attributable third-party statements.*** Plaintiff fails to plead a predicate act based on allegedly false statements made by third parties because, in Michigan, “[t]he test of whether an agency has been created is whether the principal has a right to control the actions of the agent.” *Meretta v. Peach*, 491 N.W.2d 278, 280 (Mich. Ct. App. 1992); *see also St. Clair Intermediate Sch. Dist. v. Intermediate Ed. Ass’n*, 581 N.W.2d 707 (Mich. 1998). Plaintiff has failed to plead facts sufficient to establish such control.

XI. ALL CLAIMS SHOULD BE DISMISSED, IN PART, AS TIME-BARRED.

Plaintiff’s claims rely largely on alleged acts or omissions that occurred as far back as the mid-1990s. *See, e.g.*, 2AC ¶¶ 116, 152, 219, 267. But each claim is subject to a statute of limitations, and the *longest* such limitations period is six years.¹⁰ Plaintiff’s claims accrued “at the time the wrong upon which the claim is based was done regardless of the time when damage results.” MCL § 600.5827. Accordingly, the Court should dismiss Plaintiff’s claims to the extent they rely on alleged conduct committed before February 7, 2012—six years before Plaintiff brought suit—by defendants named in the original complaint, and before April 25, 2012 by defendants first named in the amended complaint.

A. No Exception to the Limitations Periods Applies.

The 2AC attempts to avoid dismissal of Plaintiff’s claims as time-barred by citing three exceptions to the limitations period: continuing violation, fraudulent concealment, and equitable estoppel. *See* 2AC ¶¶ 685-95. None applies.

¹⁰ *Boyle v. Gen. Motors Corp.*, 661 N.W.2d 557, 558 (Mich. 2003) (six-year period for fraud); MCL § 445.911(7) (six-year period for MCPA); *K-Mart Corp. v. Logan*, 2003 WL 21583385, at *8 (Mich. Ct. App. July 10, 2003) (six-year period for civil conspiracy and unjust enrichment when gravamen of complaint sounded in fraud). The remaining claims are subject to either a four-year period, *Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156 (1987) (four-year period for RICO claim), or a three-year period, MCL § 600.5805(10) (injury to a person or to property); *id.* § 600.5805(13) (products liability claims).

1. The Continuing Violation Doctrine Has Been Abrogated by Statute.

The Michigan Legislature has codified a comprehensive statutory scheme that provides “tolling of the period of limitations in certain specified situations.” *Trentadue v. Buckler Lawn Sprinkler*, 738 N.W.2d 664, 670 (Mich. 2007). Because the Legislature did not provide for the continuing violation doctrine within that statutory scheme, the doctrine has been abrogated and held as “contrary to Michigan law.” *See id.* at 670-71; *Garg v. Macomb Cty. Cmty. Mental Health Servs.*, 696 N.W.2d 646, 658-59 (Mich.), *as amended* 699 N.W.2d 697 (Mich. 2005). Thus, the continuing violation doctrine does not apply.

2. The Fraudulent Concealment and Equitable Estoppel Doctrines Do Not Apply.

Both the fraudulent concealment and equitable estoppel doctrines do not apply when a plaintiff is, or should be, aware of a “possible cause of action” and cannot justifiably rely on the conduct of defendants to delay in filing a lawsuit. *See Doe v. Bishop Foley Catholic High Sch.*, 2018 WL 2024589, at *8-10 (Mich. Ct. App. May 1, 2018). As in *Summit*, Plaintiff fails to plead facts to support either exception. To the contrary, the 2AC confirms that Plaintiff knew, or reasonably should have known, of the alleged fraud long before February 7, 2012, and that many of the materials Plaintiff relies upon in the 2AC were publicly available before 2012. *See, e.g.*, 2AC ¶¶ 130-31, 145-49, 160-63, 232, 245, 247, 276, 288, 706-07. As a result, the fraudulent concealment and equitable estoppel exceptions do not apply.

CONCLUSION

For the reasons stated above, the Court should dismiss the 2AC with prejudice.

Dated: June 8, 2018

Respectfully submitted,

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that this case has been assigned to the “litigation track” pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, and L.R. 7.1(f).

Dated: June 8, 2018

/s/ Brien T. O'Connor
Brien T. O'Connor

CERTIFICATE OF SERVICE

I hereby certify that on June 8, 2018, a copy of the foregoing **Memorandum of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Dated: June 8, 2018

/s/ Brien T. O'Connor
Brien T. O'Connor